

**EWG M2 Recommendation to the ICH Steering Committee**  
**Electronic Standards for the Transfer of Regulatory Information (ESTRI)**  
**General - Recommendation 1.3** 29APR1996

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**Title:** General 1.3 - Core Standard Set

**Date:** 29 April 1996

**Background:**

It is recognized that efficient electronic communication of regulatory information on an international basis will require the adoption of acceptable standards to define the transport, format, content, and security of this communication. Standards for the transport, format, and security are within the remit of the M2 Expert Working Group while content definition is the responsibility of other ICH EWGs. Due to rapidly changing nature of information technology, it is anticipated that the standards recommended by the EWG will change. Further, due to the broad scope of types and complexity of regulatory communication, it is also anticipated that new areas of standards will be continually added to and replacing those previously recommended. To accommodate these factors, the EWG has developed the concept of a core set of standards which represents the current complement of recommended and approved standards.

**Recommendation:**

The Expert Working Group recommends that the following policy for accepting the current Core Standard Set be adopted by the Steering Committee:

- The current set of recommended, approved, and implemented standards will be accepted by the Regulatory Authorities for the categories of Regulatory Communications to which they apply.
- Industry will be able to use any of the Core Standard Set with the assurance that they will be acceptable by Authorities

**Conditions:**

- Industry and Authorities may use any mutually agreeable mechanism for electronic communication in the case of information categories for which standards have not yet been adopted.

**Remarks:**

- There may instances in which Industry and Regulatory Authorities agree that it is mutually advantageous to use an approach for a particular regulatory communication which differs from the Core Standard Set. However, in all instances the Core Standard Set will define an approach which will always be accepted by the Regulatory Authorities and may always be used by Industry.
- It is expected that the Regulatory Authorities will share information about technologies being used and those being considered.

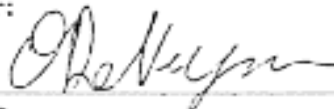
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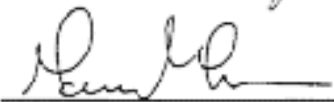
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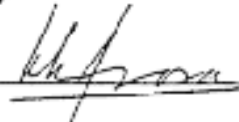
SIGNATURES

Topic Leader:

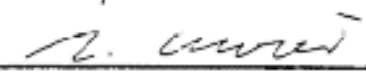
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Observer:

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